IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD. and LTS LOHMANN THERAPIE-SYSTEME AG Plaintiffs, v. PAR PHARMACEUTICAL, INC. Defendant.	:	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd. and LTS Lohmann Therapie-Systeme AG (hereinafter "Plaintiffs"), for their Complaint against defendant Par Pharmaceutical, Inc. allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Plaintiff Novartis Pharma AG ("Pharma AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. Plaintiff Novartis International Pharmaceutical Ltd. ("NIP") is a corporation organized and existing under the laws of Bermuda, having an office and place of business at 131 Front Street, Hamilton HM12, Bermuda.

6. Plaintiff LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of Germany, having an office and place of business at Lohmannstraße 2, D-56626 Andernach, Germany.

7. On information and belief, defendant Par Pharmaceutical, Inc. ("Par") is a corporation organized and existing under the laws of the State of Delaware, having an office and place of business at One Ram Ridge Road, Spring Valley, New York 10977.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

9. On information and belief, Par is incorporated in Delaware and has purposely availed itself of the rights and benefits of Delaware law and this Court.

10. On information and belief, Par is in the business of manufacturing, marketing, importing into the United States and selling pharmaceutical drug products, including

generic drug products. On information and belief, Par directly or through its affiliates and agents markets and sells drug products throughout the United States and in this judicial district, and has purposely availed itself of the rights and benefits of Delaware law and this Court.

11. This Court has personal jurisdiction over Par by virtue of, *inter alia*, the above-mentioned facts.

12. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF – PATENT INFRINGEMENT

13. Plaintiff NPC holds an approved new drug application ("NDA") No. 22-083 for Exelon® Patch (rivastigmine transdermal system or extended release film) (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths), which patch contains the active ingredient rivastigmine. Exelon® Patch (4.6 mg/24 hr and 9.5 mg/24 hr dosage strengths) was approved by the United States Food and Drug Administration ("FDA") on July 6, 2007, and Exelon® Patch (13.3 mg/24 hr dosage strength) was approved by the FDA on August 31, 2012. Exelon® Patch is indicated for the treatment of mild to moderate dementia of the Alzheimer's type and mild to moderate dementia associated with Parkinson's disease. Exelon® Patch (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths) is sold in the United States by Plaintiff NPC.

14. Rivastigmine is known chemically as (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate.

15. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,335,031 ("the '031 patent"). The '031 patent was duly and legally issued on January 1, 2002.

16. The ‘031 patent claims pharmaceutical compositions, *inter alia*, comprising: (a) a therapeutically effective amount of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in free base or acid addition salt form; (b) about 0.01 to about 0.5 percent by weight of an antioxidant, based on the weight of the composition, and (c) a diluent or carrier, as well as transdermal devices and methods of stabilizing (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in free base or acid addition salt form. A true copy of the ‘031 patent is attached hereto as Exhibit A.

17. The ‘031 patent was initially assigned to Novartis AG and LTS Lohmann Therapie-Systeme GmbH & Co. KG, which subsequently changed its legal form to become Plaintiff LTS.

18. On information and belief, Par submitted to the FDA an abbreviated new drug application (“ANDA”) under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, and sale of a rivastigmine transdermal system, 13.3 mg/24 hr dosage strength (“Par’s ANDA Product”) before the expiration of the ‘031 patent.

19. On information and belief, Par made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the ‘031 patent is invalid and/or will not be infringed.

20. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Par’s ANDA Product before the expiration of the ‘031 patent, Par has committed an act of infringement under 35 U.S.C. § 271(e)(2).

21. On information and belief, when Par filed its ANDA, it was aware of the '031 patent and that the filing of its ANDA with the request for its approval prior to the expiration of the '031 patent was an act of infringement of that patent.

22. On information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Par's ANDA Product will infringe one or more claims of the '031 patent.

23. On information and belief, the commercial manufacture of Par's ANDA Product will involve direct infringement of the '031 patent. On information and belief, this will occur at Par's active behest, and with Par's intent, knowledge and encouragement. On information and belief, Par will actively induce, encourage and abet this infringement with knowledge that it is in contravention of the rights under the '031 patent.

24. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to Par's ANDA Product be a date that is not earlier than January 8, 2019, the expiration date of the '031 patent, and an award of damages for any commercial sale or use of Par's ANDA Product and any act committed by Par with respect to the subject matter claimed in the '031 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

25. On information and belief, Par has taken and continues to take active steps towards the commercial manufacture, use, offer for sale, sale and/or importation of Par's ANDA Product, including seeking approval of that product under Par's ANDA.

26. There is a substantial and immediate controversy between Plaintiffs and Par concerning the '031 patent. Plaintiffs are entitled to declaratory judgment under 28 U.S.C.

§§ 2201 and 2202 that Par will infringe and/or induce infringement of one or more claims of the '031 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Par has infringed and induced infringement of one or more claims of the '031 patent by filing the aforesaid ANDA relating to Par's rivastigmine transdermal system, 13.3 mg/24 hr dosage strength;

B. A permanent injunction restraining and enjoining Par and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of a rivastigmine transdermal system, 13.3 mg/24 hr dosage strength, as claimed in the '031 patent;

C. An order that the effective date of any approval of the aforementioned ANDA relating to Par's rivastigmine transdermal system, 13.3 mg/24 hr dosage strength, be a date that is not earlier than the expiration of the right of exclusivity under the '031 patent;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of Par's rivastigmine transdermal system, 13.3 mg/24 hr dosage strength, will infringe one or more claims of the '031 patent and that Par will induce infringement of one or more claims of the '031 patent;

E. Damages from Par for the infringement and inducement of infringement of the '031 patent;

F. The costs and reasonable attorney fees of Plaintiffs in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: August 22, 2013

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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